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Indian Standard

SPECIFICATION FOR ELECTROENCEPHALOGRAPH (EEG)

PART 2 PERFORMANCE REQUIREMENTS

UDC 616·831 — 073·97 : 620·16

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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SPECIFICATION FOR ELECTROENCEPHALOGRAPH (EEG)

PART 2 PERFORMANCE REQUIREMENTS

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Indian Standard

SPECIFICATION FOR ELECTROENCEPHALOGRAPH (EEG)

PART 2 PERFORMANCE REQUIREMENTS

0. FOREWORD

0.1 This Indian Standard (Part 2) was adopted by the Indian Standards Institution on 13 May 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 Human brain has an electrical rhythm which is intrinsic in nature and not related to mechanical movement from the blood vessels. There is dominant rhythm in the brain of human which changes with age, sensory stimuli and diseases. The electroencephalograph is a powerful tool to record for detecting abnormalities in the brain like brain tumours, brain injury, epilepsy, etc.

0.3 While Part 1 of this standard [IS : 11302 (Part 1)-1985] specifies general and safety requirements of electroencephalograph, this standard (Part 2) specifies the performance requirements. Legend of symbols of figures is given in Appendix A of Part 1 of this standard.

0.4 In the preparation of this standard (performance requirements) assistance was taken from IEC 62D (Secretariat) 33 Medical Electrical Equipment Electroencephalograph, Part 3 Particular requirements for performance.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard (Part 2) specifies the particular performance requirements for electroencephalographs and their associated accessories,

---

*Rules for rounding off numerical values (*revised*).

intended for the production of detachable graphic recording of electrical activity of the brain for diagnostic purposes.

1.2 Special requirements concerning other equipments in electroencephalography, such as phono-photic stimulators, EEG telemetry, EEG Data Storage and Retrieval, EEG monitoring of the critically ill, etc, are not covered by this standard.

2. TEST, TRANSPORT, STORAGE AND OPERATING CONDITIONS

2.1 Test Conditions

2.1.1 Unless otherwise stated tests shall be carried out with the accessories and the recording materials specified by the manufacturer.

2.1.2 Unless otherwise stated tests shall be carried out under the conditions specified in Part 1 of this standard.

2.1.3 Unless otherwise stated, all tests shall be carried out under the following 'standard conditions for tests':

a) With any supply power frequency rejection filter switched off;

b) Sensitivity of 10 μV/mm;

c) Time constant of 1 s (or less); and

d) Upper frequency setting between 50 Hz and 100 Hz.

2.1.3.1 Equipment with an internal electrical power source shall be tested with the maximum and minimum internal power source voltage specified by the manufacturer.

2.1.4 Unless otherwise stated the values of components used in tests circuits shall have an accuracy as given below:

Resistors	± 1 percent
Capacitors	± 5 percent
Inductors	± 10 percent
Test voltages	± 1 percent

2.1.5 *Type Tests* — The test conditions which are necessary during the type tests are given in the Appendix A.

These have been specified so as to reduce the number of tests required, for example, in some cases testing is required only at 90 percent of the rated voltage.

However, if inspection of the construction used shows that compliance with a particular requirement is unlikely to be met, then additional testing, for example, at 110 percent of the rated voltage may be required.

2.2 Transport and Storage

2.2.1 The requirements of this standard apply:

a) to electroencephalograph which is capable of being transported and stored under environmental conditions not exceeding those specified by the manufacturer.

b) in the absence of such specifications, to electroencephalographs which, while packed for transport and storage, is capable of being exposed for a period not exceeding 15 weeks to environmental conditions not exceeding the following:

1) an ambient temperature between —40 and +70°C;

2) a relative humidity between 10 and 100 percent, including condensation; and

3) an atmospheric pressure between 500 and 1 060 millibar.

If the period of transportation and storage of such equipment exceeds 15 weeks, environmental conditions as specified in **2.3** apply.

2.3 Operating Conditions — The requirements of this standard apply to electroencephalographs which are specified for normal use under the following conditions:

a) Mains voltage fluctuations ±10 percent of nominal voltage;

b) Mains frequency fluctuations ±1 percent of nominal frequency;

c) Temperature range 10 to 40°C;

d) Relative humidity 25 to 95 percent (without condensation);

e) Altitude/atmospheric pressure (700-1 060 m bar); and

f) Mechanical robustness (bumps, vibration) (*under consideration*).

2.4 Electroencephalographs shall function satisfactory over the full range of the operating conditions as listed in **2.3**.

3. INSTRUCTIONS FOR USE

3.1 The instructions for use shall contain the following particular performance requirements, specified in **3.2** to **3.6**, in addition to the requirements specified in Part 1 of this standard.

3.2 Advice and Precautions to Avoid External Interference — Attention should be drawn to the choice of electrodes in order to avoid excessive dc offset-voltages (*see* **7.8**).

3.3 Reduction of frequency bandwidth and quality of the recording involved with the use of the filter (*see* **9.1** and **9.3.3**).

3.4 Quality and reference number of the recording paper (*see* **9.2**).

3.5 Data for signal input and output (if present), pin configuration of the connectors (*see* Appendix B).

3.6 Instructions for the alignment of the writing points (*see* **10.2.3**).

4. INPUT CIRCUITS

4.1 Number of Electrode Lead Terminals – The minimum number of electrode lead terminals shall be 23 plus neutral. It is recommended that auxiliary electrode lead terminals be provided for recording ECG and EMG.

4.2 Electrode Identification — The electrode lead terminals shall, whatever type of symbol or number sequence is employed, clearly identify each electrode lead, and markings shall correspond exactly with those indicated by the input selector.

The neutral electrode lead shall be marked N.

4.3 Patient Cables and Plugs — The overall length of the cable from the electrode lead terminal box to the electroencephalograph shall not be less than 4 m.

4.4 Input Selector

4.4.1 Each electrode lead terminal shall be capable of being connected to either input of every EEG recording channel.

4.4.1.1 The indication of the input selector shall be identical with that at the electrode lead terminal box.

4.4.1.2 The indication of the input selector shall clearly identify the electrode lead terminals connected to the input terminal 1 and input terminal 2.

4.4.2 An average potential reference should be provided.

4.4.3 Where a montage selector is provided the input selector may be omitted if means are provided for the optional fitting of an input selector.

4.5 Recovery Time

4.5.1 Means shall be provided for the trace to be restored within 2 s manually or automatically at any time constant to its initial position ±15 percent of the effective recording width following input selector switching between EEG electrodes having a 300 mV dc voltage difference at a sensitivity of 10 μV/mm.

4.5.2 Using the test arrangement in Fig. 1, at a sensitivity of 10 μV/mm, three minutes after applying 300 mV dc of either polarity between two EEG electrodes, any one channel shall be switched from short-circuited position to these electrodes.

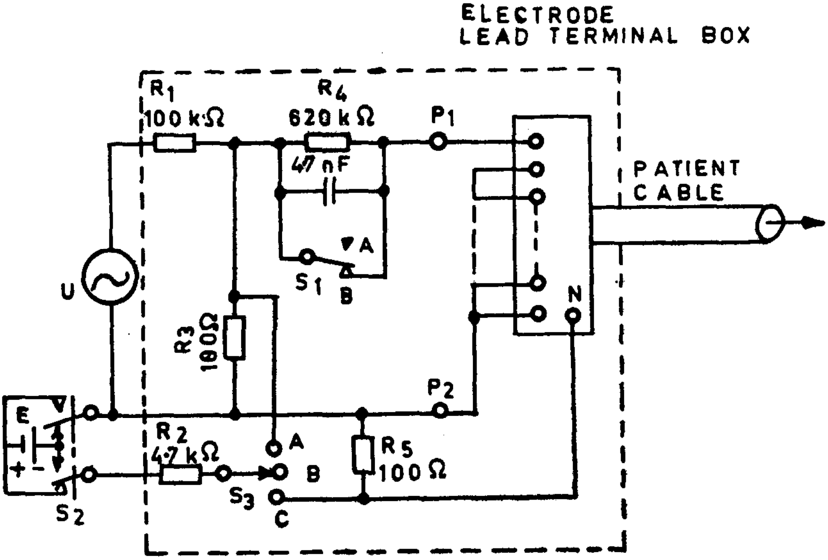

Fig. 1 Test Arrangement for Recovery Time (**4.5**) and Input Impedances (**4.7**)

At any time constant, the time taken for the trace to recover to the initial position within ±15 percent of the effective recording width shall not exceed 2 s.

4.5.3 Repeat with the polarity of the test voltage reversed.

4.6 Electrode Impedance Measurement

4.6.1 Means shall be incorporated to indicate the impedance of each electrode. The measurment shall be made at any frequency of 10 ± 2 Hz. The indication shall be within ± 20 percent of its actual value for values between 1 and 50 k ohm. The measuring current shall be less than 10μA.

4.6.2 The measurement of the above parameters shall be performed before substituting the electrode impedance by known values of resistors. The term electrode impedance implies the resistance between two electrodes and includes skin resistance.

4.7 Input Impedances

4.7.1 Over a frequency range determined by the longest time constant and the upper frequency limit at a setting between 50 and 100 Hz a test impedance of 620 k ohm resistor in parallel with a 4·7 nF capacitor inserted in series with any electrode shall not result in a signal reduction of more than 40 percent of that without the simulated impedance.

This approximates at 10 Hz to a single ended input impedance of 1 megohms.

This requirement shall be met in the presence of differential and common mode dc offset voltages. These offset voltages shall not be applied simultaneously.

4.7.1.1 Compliance shall be checked by the test (*see* Fig. 1) in **4.7.2**.

4.7.2 With S_3 in position A adjust the voltage E to give a dc offset of 300 mV across R_3 and R_5.

The sensitivity of the electroencephalograph shall be 10 μV/mm.

Connect point P_1 in the diagram to an arbitrary electrode position in the electrode lead terminal box using the input or montage selector and switch input terminal 1 of an EEG channel to this electrode position. Switch terminal 2 of the same channel to all the other EEG electrodes connected together (point P_2 in the diagram).

With S_3 and S_1 in the B-position adjust the voltage U to make a peak to valley deflection of 10 mm at any single frequency within the frequency range described in the requirement. With S_1 in position A the peak to valley deflection shall not be less than 6 mm.

Repeat with S_3 in A and C position and S_2 in both positions.

Repeat with input Terminal 1 and 2 reversed.

If an average potential reference is provided, repeat with P_1 connected to any arbitrary EEG electrode position and input terminal 1 of any EEG channel.

Input terminal 2 shall be switched to the average potential reference, which shall be selected using the maximum number of contributing electrodes. In this case the peak to valley deflection shall not be less than 5 mm.

The generator U must have an isolated output.

When BF or CF equipment is tested the screening closure may be grounded.

4.8 Patient Auxiliary Current — With all other electrodes connected together, the dc current into any EEG electrode (except the neutral electrode) shall not exceed 0·1 μA. Compliance shall be checked by the following test:

a) Connect one EEG electrode lead terminal to P_1 of Fig. 2.

b) Connect all other EEG electrodes except one [mentioned in (a)] to P_2 of Fig. 2.

c) Measure the dc voltage with voltmeter V in parallel with R_6. This dc voltage shall be less than 10 mV.

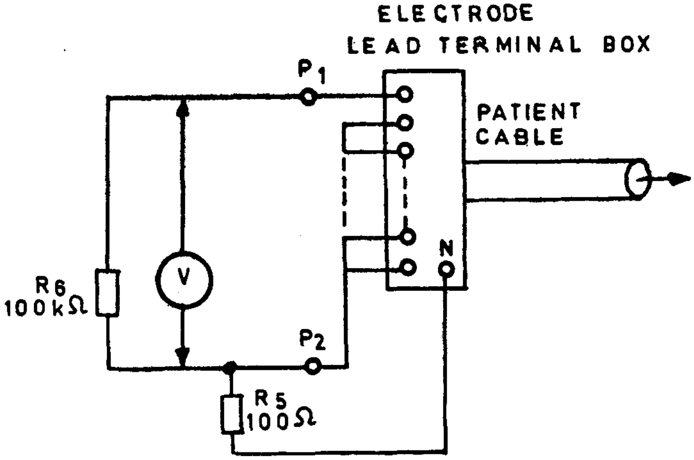

FIG. 2 TEST FOR PATIENT AUXILIARY CURRENT

5. CALIBRATION VOLTAGE

5.1 A step-function calibration signal having a rise and fall time not greater than 1 ms and an amplitude of 5, 10, 20, 50, 100, 200, 500, 1 000 μV referred to the input should be provided in steps as a routine test.

5.2 The calibration voltage shall check the functioning of the complete electroencephalograph including electrode pre-amplifier, if any.

5.3 The calibration voltage shall be added before any ac-coupling determining the time constant and before any control accessible by the user (for example filter and sensitivity).

5.4 Where the calibration voltage does not check the overall sensitivity, including any electrode pre-amplifier, means shall be provided for the operator to carry out such a test.

5.5 The maximum error of the calibration voltage shall not exceed a value of ±2 percent or 2 μV whichever is greater.

5.5.1 Compliance with **5.1** and **5.5** shall be checked on the recording by comparison with the trace produced by an external step-function voltage having a rise and fall time not more than 1 ms and an amplitude corresponding to the steps of the internal calibration voltage and an accuracy of ±2 percent or ±0·2 μV whichever is the least.

5.6 Where the calibration voltage is derived from a charged capacitor, for example, to comply with the requirements of **5**, the calibration circuit shall have a time constant of not less than 100 seconds.

5.6.1 Compliance shall be checked by inspection of the circuit arrangement.

6. SENSITIVITY

6.1 The maximum sensitivity shall not be less than 1 μV/mm at 10 Hz and at maximum bandwidth.

6.2 An independent control of the sensitivity shall be provided for each channel covering the range 1-100 μV/mm in steps of not more than 1 : 2 with an accuracy within ±5 percent. Additionally and alternatively a master step control shall be provided common to all EEG channels covering at least the range 1-30 μV/mm in steps not more than 1 : 2.

6.3 Compliance shall be checked by recording an external test voltage, covering 10-1 000 μV in steps corresponding to those of the equipment with a maximum error of ±1 percent. If a sensitivity trimming control is provided, it shall not be readjusted during the test. This test shall be performed in presence of ±300 mV differential and common mode dc offset voltage. These voltages shall not be applied simultaneously.

7. REQUIREMENTS TO REDUCE THE EFFECTS OF UNWANTED EXTERNAL VOLTAGES

7.1 Common Mode Rejection — The electroencephalograph shall meet the following test for the rejection of unwanted external interference appearing on the patient.

7.1.1 A 50 or 60 Hz signal of 10 Vrms applied according to Fig. 3 with a 22 k ohm resistor in parallel with a 3 300 pF capacitor simulated unbalance in the electrode impedance shall not produce a maximum recorded (disturbed) output signal greater than 10 mm peak to valley at 'Standard conditions for tests' (*see* **3.1**).

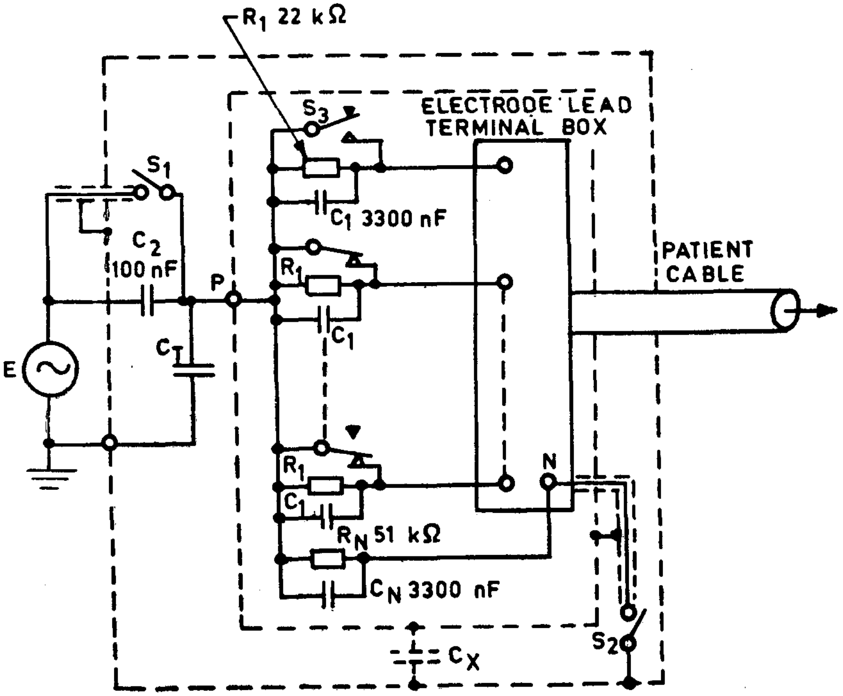

FIG. 3 TEST FOR COMMON MODE REJECTION

Switches S_1 and S_2 open.

Signal source *E* adjusted to 10 Vrms, 50 or 60 Hz.

Input terminal 1 of an arbitrary channel connected to an electrode lead where switch S_3 is open, the input terminal 2 of the same channel connected to all other electrode leads being short-circuited at the electrode lead terminal box and for which all corrosponding switches S_3 are short-circuited.

Repeat with input terminals 1 and 2 reversed.

Repeat the procedure with any other EEG channel.

If an average potential reference is provided, repeat with input terminal 2 connected to this reference instead of the short-circuited electrode leads.

7.2 The electroencephalograph shall meet the following test for the rejection of common mode signals originating in the patient.

7.2.1 A 10 Hz sinusoidal signal of 5 mV peak to valley applied according to Fig. 3, where switches S_1 and S_2 are short-circuited and with a 22 k ohm resistor in parallel with a 3 300 pF capacitor simulated unbalance in the electrode impedance shall not produce a maximum recorded output signal greater than 10 mm peak to valley at 'Standard conditions for tests' (*see* **3.1**).

Switches S_1 and S_2 short-circuited.

Signal source E adjusted to 5 mV peak to valley, 10 Hz sinusoidal.

Connection of input terminals 1 and 2 as above.

7.3 Ability of EEG Equipment to Reject rf Interference (for Example, Diathermy Sources) — Requirements and test are under consideration.

7.4 Overload Tolerance

7.4.1 Differential input circuit voltage of 1 V peak to valley shall not damage the electroencephalograph.

7.4.2 The equipment shall withstand a differential input voltage of 1 V peak to valley applied between the electrode lead terminals of any three adjacent channels. The test signal shall be at any rated supply frequency for 10 s applied such that the deflections of the adjacent channels of the recording system are in antiphase.

The test shall be carried out 5 times with at least 10 s interval between tests (type test) at standard conditions for tests. There shall be no mechanical damage to the recording system.

7.5 The Effect of Transients on the Mains-Supply — Requirements and tests under consideration.

7.6 Magnetic Interference — Mains frequency magnetic fields shall not produce an excessive interference on the record.

Compliance shall be checked by measurement as follows:

The electroencephalograph is tested without patient cable (input short-circuited at the electrode lead terminals) in an environment of 1×10^{-6} T peak at 55 Hz.

The amplitude of the recording shall be less than 1 mm peak to valley at standard conditions for test.

7.7 Protection Against the Effects of a Cardiac Defibrillator Discharge — Where means are incorporated for protection against the effects of the discharge of a cardiac defibrillator, the electroencephalograph shall meet the requirements of this standard after application of the test methods as required in Part 1 of this standard.

7.8 Differential and Common Mode dc Offset Voltage

7.8.1 With 300 mV dc offset differentially applied to the EEG electrodes the requirements of **4.6**, **4.7**, **6.1**, **7.1**, **7.2**, **8.5**, **8.6**, **9.1** and **9.4** shall be met.

7.8.2 With 300 mV of either polarity applied between the neutral electrodes and all EEG electrodes connected together the requirements of **4.6**, **4.7**, **6.1**, **7.1**, **7.2**, **8.5**, **8.6**, **9.1** and **9.4** shall be met.

8. BASE LINE

8.1 Trace Width — The trace width shall not exceed 0·5 mm.

8.1.1 Compliance shall be checked by measurement.

8.2 Base Line Shift Control — An electrical base line shift control should be provided for each channel the range of control of which is not less than the maximum peak to valley deflection of the writers.

8.3 Stability — After an initial warm-up period of 1 min, the base line shall not drift by more than 5 mm within the next 5 min. The total base line drift during the next 5 hours shall not exceed the capability of any base line shift control at 'Standard conditions for tests' (*see* **2.1**). In the case of electroencephalographs without base line shift control the total base line drift during a period of 5 hours following a warm-up period of 1 min shall not exceed ±10 percent of the effective recording width at 'standard conditions for tests'.

Compliance shall be checked by measurement.

8.4 Temperature Drift

8.4.1 At an ambient temperature range between 10°C and 40°C the base line position temperature coefficient, expressed as a percentage of the effective recording width, shall not exceed 1·5 percent °C at 'Standard conditions for tests'.

8.4.2 Compliance shall be checked by measurement.

8.5 Noise Level

8.5.1 With the electrode lead terminals connected through 4·7 k ohm metal film resistors to the neutral electrode lead terminal at 'Standard conditions for tests', intermittent or transient deflections individually greater than 4 mm peak to valley shall not on average appear more often than once per minute, and those greater than 2 mm shall not on average appear more often than once per second. Base line wander shall be less than 1·5 mm peak to valley, measured over any period of 6 s.

8.5.2 Compliance shall be checked by measurement over a period of 10 minutes.

8.6 Interaction Between Channels

8.6.1 A sinusoidal input of 1 mV peak to valley at a frequency of 40 Hz into one channel with the sensitivity set to give 10 mm deflection peak to valley shall not produce a deflection greater than 0·5 mm peak to valley in the other channels when they are connected to the neutral electrode lead terminal via 4·7 kohm resistors at 'Standard conditions for tests'. This requirement does not apply, where independent sensitivity controls of each channel are not provided.

8.6.1.1 Compliance shall be checked by measurement.

8.6.2 With a 10 Hz sinusoidal signal applied in phase to all channels, except one, the input of which is connected to the neutral electrode, so as to produce a deflection equal to the effective recording width. The deflection in the channel under test shall be less than 0·5 mm at standard conditions for tests.

Each chanel shall fulfil this requirement.

8.6.2.1 Compliance shall be checked by measurement.

8.7 Sensitivity/Base Line Interaction — The adjustment of any sensitivity control, accessible without the use of a tool, shall not produce a base line shift exceeding ±5 percent of the effective recording width of the channel set a maximum time constant under test.

8.7.1 Compliance shall be checked by measurement.

9. DISTORTION

9.1 Amplitude Frequency Characteristics

9.1.1 The manufacturer shall specify the amplitude frequency characteristic.

9.1.2 The amplitude frequency characteristic at all filter settings shall be specified in a graphical form, in the accompanying documents, showing the tolerance limits as illustrated in Fig. 4.

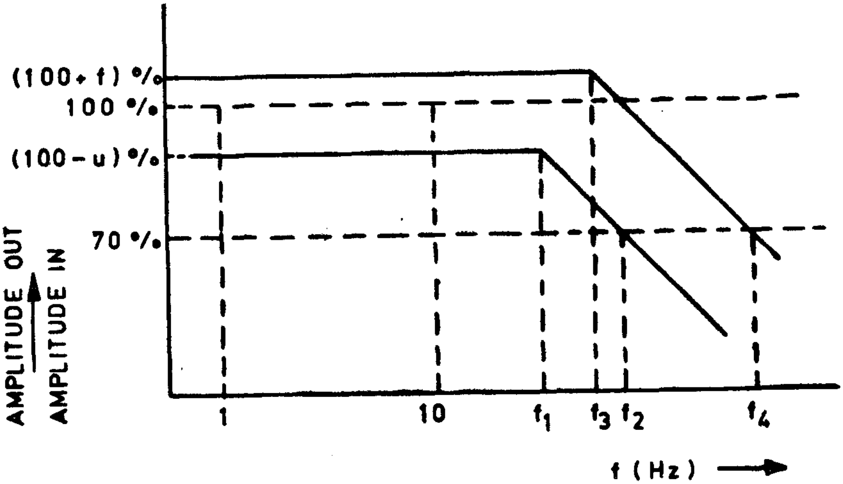

FIG. 4 AMPLITUDE-FREQUENCY CHARACTERISTICS

A separate graph shall be provided for each setting of a high frequency filter, if present (*see* **9.4**).

9.1.3 The electroencephalograph shall be tested with a sinusoidal signal applied to the equipment via the electrode lead terminal box at a sensitivity of 10 µV/mm.

The test signal shall produce a peak to valley deflection of 10 mm at 10 Hz in the centre of the effective recording width. Between the limits of 1 and 60 Hz, the amplitude response of the recorded output shall be the same as that of 10 Hz, within ±10 percent or 0·25 mm, whichever is larger.

If the response of the recorded output signal extends beyond 60 Hz, then the amplitude shall not increase by more than 20 percent of the response at 10 Hz.

9.2 Damping and Overshoot — With the base line centred, at the longest time constant provided and high frequency filter setting to between 50 and 100 Hz and at a sensitivity of 10 µV/mm any overshoot in response to a step function input of 100 µV of either polarity, having a rise time not exceeding 1 ms, shall not exceed 1 mm in amplitude.

The stated performance may be adversely affected if recording paper having a specification other than that recommended by the manufacturer is used.

9.3 Low and High Frequency Filters

9.3.1 *Time Constant of Low-Frequency Filter*

9.3.1.1 After the application of a step-function input signal the decay of the first 140 ms shall not exceed that produced by a filter setting of 0·15 Hz (which approximates to a time constant of 1 s).

9.3.1.2 Compliance shall be checked by inspection and the following test. At 'Standard conditions for tests', a step-function signal of 100 µV amplitude having a rise-time not greater than 5 ms is applied to the input. The decay of the response measured on the recording over the period 40 to 240 ms after the input step, shall not exceed 2 mm (*see* Fig. 5).

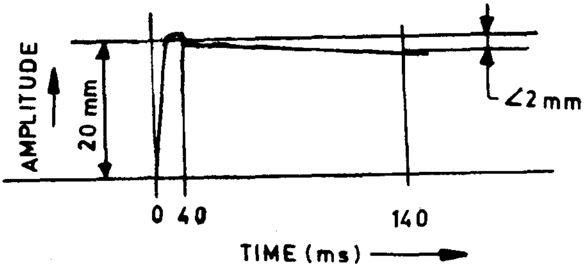

FIG. 5 TEST OF LOW-FREQUENCY PERFORMANCE

9.3.1.3 Additional selectable filter settings 0·5 Hz and 1·5 Hz are recommended which approximates to time constants of 0·3 and 0·1 s.

9.3.1.4 Low frequency controls shall be marked in frequency (Hz) and may additionally be marked in seconds, indicating the equivalent time constant.

The time marking shall indicate the time taken for a step function having a rise time less than 1 ms to decay to 0·37 of its initial value.

9.3.2 *High Frequency Filters*

9.3.2.1 High frequency response controls shall be provided. High frequency response controls should provide cut-off frequencies (–3 dB) of 60, 30, 15 Hz (±10 percent).

9.3.2.2 The controls shall be marked in frequency indicating the 0·7 amplitude point referring to 10 Hz amplitude under standard conditions of test.

9.3.2.3 Compliance shall be checked by inspection and test.

9.3.3 *Filter-Switching*

9.3.3.1 Appropriate means for switching the low and high frequency response shall be provided for each channel separately.

However, for electroencephalographs complying with **4.4.3**, master controls common for all EEG channels may be used instead of individual controls to adjust the low and high frequency response.

9.3.3.2 Filter characteristics shall be described in dB/octave in the instructions for use, the response shall be the same within 1 dB for all channels.

9.3.3.3 Compliance of **9.3.3** shall be checked by inspection and test.

9.4 Linearity

9.4.1 With an input signal producing a peak to valley deflection of 5 mm at the centre of the effective recording width the recorded amplitude shall not change by more than ±0·5 mm when the signal is shifted over the whole or the effective recording width.

9.4.2 A sinusoidal signal at a frequency of 40 Hz producing a peak to valley deflection of 5 mm at the centre of the effective recording width at the lowest sensitivity provided, is shifted over the whole of the effective recording width by superimposing a 1 Hz sine wave of variable amplitude.

9.4.3 The width of the deflection measured as indicated in Fig. 6 in various positions shall not deviate by more than ±0·5 mm.

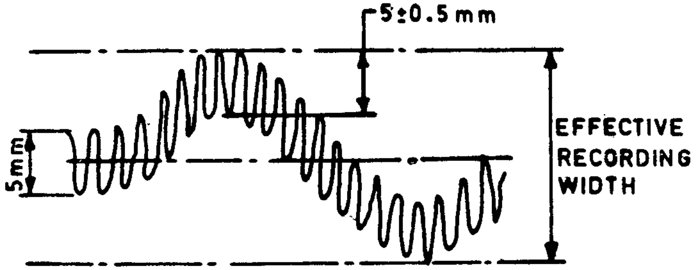

FIG. 6 WIDTH OF DEFLECTION

9.5 Response to Minimum Signal

9.5.1 A 10 Hz sinusoidal signal having an amplitude calculated to give peak to valley deflection of 0·2 mm at the lowest sensitivity provided shall yield a visible recording at a paper speed of 30 mm/s.

9.5.2 The response shall be checked by inspection of the recording.

9.6 Hysteresis

9.6.1 Hysteresis in the recording system shall not exceed 0·5 mm after a deflection of 10 mm in either direction according to the test.

9.6.2 At maximum bandwidth and 30 mm/s paper speed a 1 Hz symmetrical rectangular waveform via a 50 ms differentiating circuit shall be applied to the input to produce a ±10 mm deflection from the centre of the recording.

Successive base lines shall return to within 0·5 mm of each other (*see* Fig. 7).

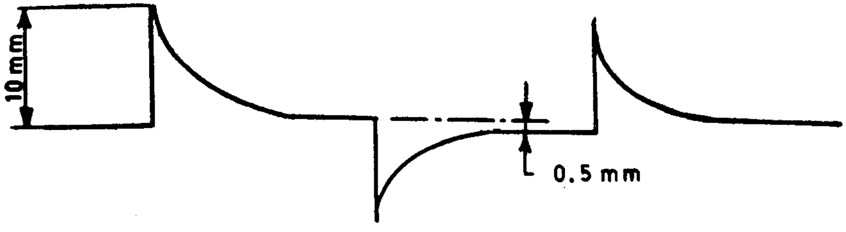

FIG. 7 HYSTERESIS MEASUREMENT

10. EEG RECORDING (WRITE-OUT)

10.1 Dimensions — The recording paper shall be z-folded and legible at the recording point and for not less than 60 cm from the recording point.

10.2 Paper

10.2.1 If rectangular coordinates are used the departure from perpendicular alignment of the line drawn by each of the writing points shall be less than 0·5 mm to a peak to valley deflection of 20 mm.

With the recording paper stationary and an input which produces a deflection of ±10 mm from the centre of the effective recording width the resulting deflection shall be parallel within 0·5 mm to a line perpendicular to the direction of the paper transport (*see* Fig. 8).

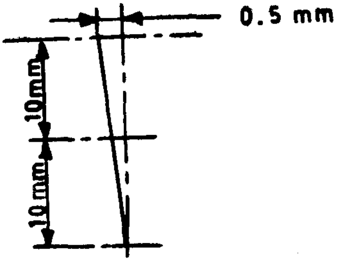

FIG. 8 EEG RECORDING

10.2.2 If a curvilinear write-out is used, the distortion of the writer shall not be more than that produced by a pen 100 mm long.

10.2.3 At zero deflection the writing points of all channels including any event markers shall be within 1 mm of a line perpendicular to the direction of paper transport. This may be checked by giving a simultaneous step signal.

10.2.3.1 Compliance shall be checked by giving a simultaneous step signal to all channels.

10.3 Time and Event Markers — A time marker having an accuracy of ±2 percent shall be provided independent of the paper drive mechanism shall be provided.

An event marker may also be provided.

The time marker and event marker, if provided, shall not produce unwanted deflections in any channel greater than 0·2 mm at any sensitivity.

10.4 Recording Speed

10.4.1 Three speeds 15, 30 and 60 mm/s under the worst combinations of the conditions specified in **2.1** and **2.3** shall be provided.

10.4.2 Tolerance for these speeds shall be ±5 percent.

10.4.3 Compliance with speed selection requirements shall be established by visual inspection and operation of the speed selection mechanism. The recording speed accuracy shall be determined by connecting a signal generator at any convenient channel of the EEG device and adjusting the amplitude of a triangular signal such as to generate a 5 mm peak to valley signal at 30 Hz ± 1 percent.

10.4.3.1 At a recording speed of 30 mm/s and after not less than 1 s of running time, examine five consecutive sequences of 10 cycles each. Each sequence of 10 cycles shall occupy 10 ±0·5 mm measured without reference to the paper ruling. The distance occupied on the paper by 50 cycles shall be 50 ± 2·5 mm.

10.4.3.2 The above test shall be repeated at 15 mm/s and 60 mm/s using a test signal of 15 Hz ± 1 percent and 60 Hz ± 1 percent, respectively.

10.5 Effective Recording Width

10.5.1 The effective recording width shall be at least 20 mm.

10.5.2 Compliance shall be checked by inspection.

11. SIGNAL INPUT AND SIGNAL OUTPUT

11.1 The provision of signal input and signal output is recommended. The arrangement is shown in Appendix B.

APPENDIX A

(*Clause* 2.1.5)

TEST CONDITIONS FOR TYPE TESTS

A-1. The test conditions necessary to check compliance with the requirements of this standard are given in Tables 1 and 2.

A-2. Since the time consuming tests are those with increase or decrease of temperature and/or relative humidity only the following temperature/humidity conditions are used.

A-3. Also the mains voltage frequency is indicated with a letter (L, N or H).

TABLE 1 TEST CONDITIONS

(*Clause* A-1)

	TEMPERATURE (°C)	RELATIVE HUMIDITY, PERCENT	BAROMETRIC PRESSURE	MAINS VOLTAGE, PERCENT	MAINS FREQUENCY, PERCENT
Low (L)	10	25	Ambient	90	98
Normal (N)	20	65	Ambient	100	100
High (H)	40	95	Ambient	110	102
Tolerance	±2	±5		of rated mains voltage	or rated mains frequency

TABLE 2 TEST CONDITIONS FOR INDIVIDUAL TEST

(*Clause* A-1)

TEMP/RH	TEST	CLAUSE	VARIABLE TEST VALUE								
			Mains Voltage			Mains Frequency			dc Offset – 300 mV/0/ + 300 mV		
			L	N	H	L	N	H			
L/L	Calibration	(5)	x		x		x			x	
L/L	Sensitivity	(6.1)	x		x		x		x		x
L/L	Recording speed	(10.4)	x		x	x		x		x	
L/N	Temperature drift	(8.4)		x			x			x	
N/N	Input impedance	(4.7)		x			x		x	x	x
N/N	Sensitivity	(6.1)		x			x		x	x	x
N/N	Common mode rejection	(7.1)		x			x		x	x	x
N/N	Overload tolerance	(7.4)			x		x			x	
N/N	dc offset voltage	(7.8)			x		x		x		x
N/N	Base line	(8)	x	x	x		x			x	
N/N	Distortion	(9)									
N/N	(9·1), (9·2), (9·3)			x			x			x	
N/N	Linearity	(9.4)	x				x			x	
N/N	Response to minimum signal	(9.5)	x				x			x	
N/N	Hysteresis	(9.6)	x				x			x	
N/N	EEG recording	(10)		x			x			x	
H/N	Pat. aux. current	(4.8)			x		x			x	
H/N	Temperature drift	(8.4)		x			x			x	
H/H	Calibration voltage	(5)	x		x		x			x	
H/N	Sensitivity	(6.1)	x		x		x		x		x
H/N	Recording speed	(10.4)	x		x	x		x		x	

A-4. Table 2 gives actual conditions to be applied for individual test. In Table 2 symbol (×) indicates the test conditions to be applied.

APPENDIX B

(*Clauses* 3.5 *and* 11.1)

SIGNAL INPUT AND SIGNAL OUTPUT

B-1. The arrangement should be such that the record and play-back of a magnetic tape recorder can be inserted between two successive stages of the EEG equipment.

B-2. A basic arrangement according to the Fig. 9 is recommended.

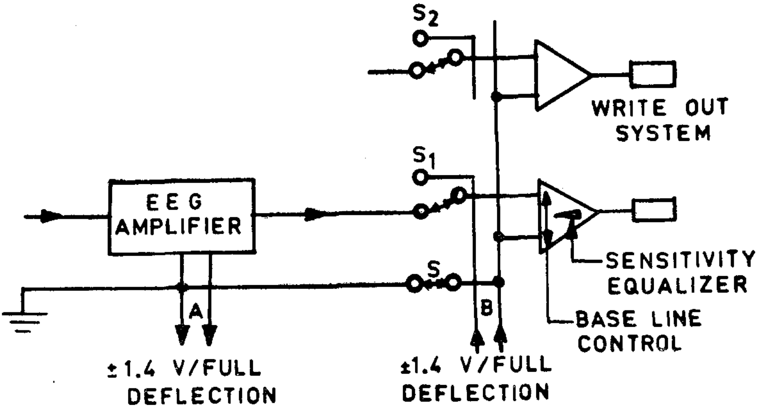

FIG. 9 SIGNAL INPUT AND SIGNAL OUTPUT

B-3. A switch over facility to ±5 V full deflection for both signal output and signal input may be added.

B-4. SIGNAL OUTPUT A

a) Single ended,

b) Output impedance — 100 ohms,

c) Load impedance — 10 k ohms,

d) Positive polarity with respect to ground for upward deflection of the base line,

e) Short circuit proof,

f) Zero voltage output for no signal input, and

g) The frequency response, the amplification long term stability and linearity, if different from that of write-out. To be indicated in the instructions for use.

B-5. SIGNAL OUTPUT B — (CONNECTION S_1, S_2 OPEN)

a) Means foreseen to enable remote grounding (connection S),

b) Means foreseen to disconnect the signal input from preceding stages (connections S_1, S_2.....),

c) Input impedance — 100 k ohms;

d) Sensitivity equalizer adjustable to include a sensitivity of 1 V/10 mm;

e) Positive polarity with respect to ground for upward deflection of the base line; and

f) Zero voltage input should give no deflection.

Class II equipment, if provided with a functional earth terminal, should be earthed during the test.

Electroencephalographs with internal electrical power source should be screened to avoid direct interference during the test.

See also **7.8** with respect to offset voltages.

R_N and C_N simulate the patients impedance to ground. In case of a Class B equipment with N connected to earth, the voltage across R_N is 45 mV which, at an unbalance of 22 k ohm in parallel with 3 300 pF, corresponds to an effective common mode rejection ratio of 450 : 1.

The test circuit of Fig. 3 includes shielding to reduce the pick-up of unwanted extraneous signals. This shielding indicated by the outer dotted line to be effective should be connected to an earth reference point. The capacitance between the shield and the measuring circuit may adversely affect the results. For this reason an internal guard shield is provided enclosing the sensitive part of the circuit. This guard shield indicated by the inner dotted line is connected to a point in the test circuit representing the common mode test voltage. The capacitance C_X between C_2 by adjusting the trimming capacitor C_T.

Thus at the common mode point *P* a voltage of 5 Vrms with a source impedance of 200 pF is provided when the electroencephalograph is not connected to the test circuit (simulating the case of a patient connected to an isolated input).

For signals originating in the patient the requirement and test corresponds to a common mode rejection ratio of 50 : 1.